

Application No.: 09/776,454

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Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 (Previously Presented): A method for testing the allergenicity of a heterologous protein produced by a plant that has been genetically modified to produce the protein, comprising the steps of:

- (a) sensitizing a newborn first atopic dog with a first extract prepared from tissue of the genetically modified plant and containing a mixture of plant proteins and the heterologous protein, by applying the first extract to the skin of the newborn first atopic dog,
- (b) after a period sufficient to allow the first atopic dog to establish an immune response to the first extract, challenging the first atopic dog with the first extract,
- (c) observing the degree of a first allergic response provoked, and if a detectable allergic response is observed,
- (d) comparing the degree of the first allergic response observed with the degree of a second allergic response in a second atopic dog observed after provoking by challenging in the same manner as in step (b) with a second extract containing substantially the same proteins as the first extract but lacking the heterologous protein, wherein said second atopic dog was sensitized as in step (a), and
- (e) if the degree of the first allergic response is greater than the degree of the second allergic response, identifying the heterologous protein as a potential allergen in humans.

Claim 2 (Previously Presented): The method of claim 1, wherein said challenging and observing steps are selected from the group consisting of:

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(a) applying the first extract to a skin region of the first atopic dog and the second extract to a skin region of the second atopic dog and observing a local wheal reaction at the application sites as the allergic responses (skin test);

(b) feeding the first extract to the first atopic dog and the second extract to the second atopic dog and observing gastrointestinal upset as the allergic responses (feeding test);

(c) contacting by injection the first extract directly with wall of the stomach of the first atopic dog and the second extract directly with the wall of the stomach of the second atopic dog and observing a local wheal reaction at the application sites as the allergic responses (gastroendoscopy test);

(d) administering the first extract by inhalation to the first atopic dog and the second extract by inhalation to the second atopic dog, and observing bronchial constriction as the allergic responses (inhalation test); and

(e) applying the first extract with a patch immobilized on the skin of the first atopic dog and the second extract with a patch immobilized on the skin of the second atopic dog and observing inflammation at the sites of application (transdermal patch test).

Claim 3 (Canceled)

Claim 4 (Previously Presented): The method of claim 1, wherein the plant is a crop plant selected from the group consisting of corn, barley, wheat, rice, peanut, sorghum, millet, spelt, and soy.

Claim 5 (Canceled)

Claim 6 (Previously Presented): The method of claim 1, wherein substantially no allergic reaction is observed in steps (c) and (d).

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Claim 7 (Previously Presented): The method of claim 1, wherein said first or second extract is prepared by forming a tissue powder and extracting the powder with a selected extract medium.

Claim 8-11 (Canceled)

Claim 12 (Previously Presented): The method of claim 1, wherein the degree of allergic response observed in step (c), compared with that observed in step (d) is indicative of the degree of allergenicity expected in humans.

Claims 13-21 (Canceled)

Claim 22 (Previously Presented): A method for testing the allergenicity of a heterologous protein produced by a plant that has been genetically modified to produce the protein, comprising the steps of:

(a) sensitizing a newborn first atopic dog with a first extract prepared from tissue of the genetically modified plant and containing a mixture of plant proteins and the heterologous protein, by injecting the first extract into the newborn first atopic dog,

(b) after a period sufficient to allow the first atopic dog to establish an immune response to the first extract, challenging the first atopic dog with the first extract,

(c) observing the degree of allergic response provoked,
and if a detectable allergic response is observed,

(d) comparing the degree of the first allergic response observed with the degree of a second allergic response in a second atopic dog observed after provoking by challenging in the same manner as in step (b) with a second extract containing substantially the same proteins as the first extract but lacking the heterologous protein, wherein said second atopic dog was sensitized as in step (a), and

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(e) if the degree of the first allergic response is greater than the degree of the second allergic response, identifying the heterologous protein as a potential allergen in humans.

Claim 23 (Previously Presented): The method of claim 22, wherein said challenging and observing steps are selected from the group consisting of:

(a) applying the first extract to a skin region of the first atopic dog and the second extract to a skin region of the second atopic dog and observing a local wheal reaction at the application sites as the allergic responses (skin test);

(b) feeding the first extract to the first atopic dog and the second extract to the second atopic dog and observing gastrointestinal upset as the allergic responses (feeding test);

(c) contacting by injection the first extract directly with wall of the stomach of the first atopic dog and the second extract directly with the wall of the stomach of the second atopic dog and observing a local wheal reaction at the application sites as the allergic responses (gastroendoscopy test);

(d) administering the first extract by inhalation to the first atopic dog and the second extract by inhalation to the second atopic dog, and observing bronchial constriction as the allergic responses (inhalation test); and

(e) applying the first extract with a patch immobilized on the skin of the first atopic dog and the second extract with a patch immobilized on the skin of the second atopic dog and observing inflammation at the sites of application (transdermal patch test).

Claim 24 (Canceled)

Claim 25 (Previously Presented): The method of claim 22, wherein the plant is a crop plant selected from the group consisting of corn, barley, wheat, rice, peanut, sorghum, millet, spelt, and soy.

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Claim 26 (Canceled)

Claim 27 (Previously Presented): The method of claim 23, wherein substantially no allergic reaction is observed in steps (c) and (d).

Claim 28 (Previously Presented): The method of claim 23, wherein said first or second extract is prepared by forming a tissue powder and extracting the powder with a selected extract medium.

Claim 29-30 (Canceled)

Claim 31 (Previously Presented): The method of claim 23, wherein the degree of allergic response observed in step (c), compared with that observed in step (d) is indicative of the degree of allergenicity expected in humans.

Claim 32 (Previously Presented): A method for testing the allergenicity of a heterologous protein produced by a plant that has been genetically modified to produce the protein, comprising the steps of:

(a) sensitizing a newborn first atopic dog with a first extract prepared from tissue of the genetically modified plant and containing a mixture of plant proteins and the heterologous protein, by feeding the first extract to the newborn first atopic dog,

(b) after a period sufficient to allow the first atopic dog to establish an immune response to the first extract, challenging the first atopic dog with the first extract,

(c) observing the degree of allergic response provoked,
and if a detectable allergic response is observed,

(d) comparing the degree of the first allergic response observed with the degree of a second allergic response in a second atopic dog observed after provoking by challenging in the same

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manner as in step (b) with a second extract containing substantially the same proteins as the first extract but lacking the heterologous protein, wherein said second atopic dog was sensitized as in step (a), and

(e) if the degree of the first allergic response is greater than the degree of the second allergic response, identifying the heterologous protein as a potential allergen in humans.

Claim 33 (Previously Presented): The method of claim 32, wherein said challenging and observing steps are selected from the group consisting of:

(a) applying the first extract to a skin region of the first atopic dog and the second extract to a skin region of the second atopic dog and observing a local wheal reaction at the application sites as the allergic responses (skin test);

(b) feeding the first extract to the first atopic dog and the second extract to the second atopic dog and observing gastrointestinal upset as the allergic responses (feeding test);

(c) contacting by injection the first extract directly with wall of the stomach of the first atopic dog and the second extract directly with the wall of the stomach of the second atopic dog and observing a local wheal reaction at the application sites as the allergic responses (gastroendoscopy test);

(d) administering the first extract by inhalation to the first atopic dog and the second extract by inhalation to the second atopic dog, and observing bronchial constriction as the allergic responses (inhalation test); and

(e) applying the first extract with a patch immobilized on the skin of the first atopic dog and the second extract with a patch immobilized on the skin of the second atopic dog and observing inflammation at the sites of application (transdermal patch test).

Claim 34 (Canceled)

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Claim 35 (Previously Presented): The method of claim 32, wherein the plant is a crop plant selected from the group consisting of corn, barley, wheat, rice, peanut, sorghum, millet, spelt, and soy.

Claim 36 (Canceled)

Claim 37 (Previously Presented): The method of claim 32, wherein substantially no allergic reaction is observed in steps (c) and (d).

Claim 38 (Previously Presented): The method of claim 32, wherein said first or second extract is prepared by forming a tissue powder and extracting the powder with a selected extract medium.

Claim 39-40 (Canceled)

Claim 41 (Previously Presented): The method of claim 32, wherein the degree of allergic response observed in step (c), compared with that observed in step (d) is indicative of the degree of allergenicity expected in humans.

Claim 42-47 (Canceled)

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